

§ 172.841

21 CFR Ch. I (4–1–02 Edition)

§ 172.841 Polydextrose.

Polydextrose as identified in this section may be safely used in food in accordance with the following prescribed conditions:

(a)(1) Polydextrose (CAS Reg. No. 68424-04-4) is a partially metabolizable water-soluble polymer prepared by the condensation of a melt which consists either of approximately 89 percent D-glucose, 10 percent sorbitol, and 1 percent citric acid or of approximately 90 percent D-glucose, 10 percent sorbitol, and 0.1 percent phosphoric acid, on a weight basis.

(2) Polydextrose may be partially neutralized with potassium hydroxide, or partially reduced by transition metal catalytic hydrogenation in aqueous solution.

(b) The additive meets the specifications of the “Food Chemicals Codex,” 4th ed. (1996), pp. 297–300, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) Polydextrose is used in accordance with current good manufacturing practices as a bulking agent, formulation aid, humectant, and texturizer in the following foods when standards of identity established under section 401 of the act do not preclude such use:

(1) Baked goods and baking mixes (restricted to fruit, custard, and pudding-filled pies, cakes, cookies, and similar baked products);

(2) Chewing gum;

(3) Confections and frostings;

(4) Dressings for salads;

(5) Film coatings on single and multiple vitamin and mineral supplement tablets;

(6) Frozen dairy desserts and mixes;

(7) Fruit and water ices;

(8) Fruit spreads;

(9) Gelatins, puddings and fillings;

(10) Hard and soft candy;

(11) Peanut spread;

(12) Sweet sauces, toppings, and syrups;

(13) Tablespreads.

(d) If the food containing the additive purports to be or is represented for special dietary uses, it shall be labeled in compliance with part 105 of this chapter.

(e) The label and labeling of food a single serving of which would be expected to exceed 15 grams of the additive shall bear the statement: “Sensitive individuals may experience a laxative effect from excessive consumption of this product”.

[46 FR 30081, June 5, 1981, as amended at 59 FR 37421, July 22, 1994; 60 FR 54425, Oct. 24, 1995; 61 FR 14480, Apr. 2, 1996; 62 FR 30985, June 6, 1997; 63 FR 57597, Oct. 28, 1998; 65 FR 64605, Oct. 30, 2000; 65 FR 79719, Dec. 20, 2000]

§ 172.842 Sorbitan monostearate.

The food additive sorbitan monostearate, which is a mixture of partial stearic and palmitic acid esters of sorbitol anhydrides, may be safely used in or on food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting stearic acid (usually containing associated fatty acids, chiefly palmitic) with sorbitol to yield essentially a mixture of esters.

(b) The food additive meets the following specifications:

Saponification number, 147–157

Acid number, 5–10

Hydroxyl number, 235–260

(c) It is used or intended for use, alone or in combination with polysorbate 60 as follows:

(1) As an emulsifier in whipped edible oil topping with or without one or a combination of the following:

(i) Polysorbate 60;

(ii) Polysorbate 65;

(iii) Polysorbate 80;

whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped edible oil topping; except that a combination of the additive with polysorbate 60 may be used in excess of 0.4 percent: *Provided*, That the amount of the additive does not exceed 0.27 percent and the amount of polysorbate 60 does not exceed 0.77 percent of the weight of the finished whipped edible oil topping.